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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,093	09/30/2003	John Rudolph Desjarlais	33604/US/2 463077-246	4088

32940 7590 12/27/2006
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EXAMINER	
SHAFER, SHULAMITH H	
ART UNIT	**PAPER NUMBER**
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	**Application No.** 10/677,093	**Applicant(s)** DESJARLAIS ET AL.
	Examiner Shulamith H. Shafer, Ph.D.	**Art Unit** 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2006*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,11,12 and 19* is/are pending in the application.
4a) Of the above claim(s) *7* is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1,11,12 and 19* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, And/Or Claims

The amendment received 12 October 2006 in response to the Office Action of 12 July 2006 has been entered. Claims 1, 7, 11, 12 and 19 are pending in the instant application. Claims 2-6 and 8-10 have been cancelled. Claim 1 has been amended and the amendment made of record. Claims 13-18 are withdrawn.

In response to requirement of species election, Applicants elected, without traverse, SEQ ID NO:35, as a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. No generic claim has been, as yet, held to be allowable. Applicants have amended claim 1 to recite "wherein said IFN has been circularly permuted or cyclized and is selected from the group consisting of SEQ ID NOs:35-49." However, since applicants have received an action on the merits for the originally presented invention, as drawn to SEQ ID NO:35, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1, 11, 12, and 19 will be examined to the extent they read on the elected species, SEQ ID NO:35.

The text of those sections of Title 35 U.S. Code not included in this action can be found in the prior Office action.

Withdrawn Objections/Rejections

The objection of Claims 3 and 5 as encompassing non-elected inventions is withdrawn in view of applicants' amendments to the claims.

All rejections of Claims 2-5 and 8 have been withdrawn; applicants have withdrawn these claims thereby rendering rejection of these claims moot.

The rejection of Claims 1-5, 8, 11, and 19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicants' amendments to the claims.

New/Maintained Objections/Rejections

Objections:

Claim 1 is objected to as being drawn to non-elected subject matter. The claim recites non-elected sequences. Appropriate correction is required.

The figures/drawings are objected to for the following reasons: the brief description of the drawings refers to Figures 4 and 5. However, these drawings could not be found in the instant application.

35 U.S.C. § 103

The rejection of Claims 1, 7, 11, 12 and 19 under 35 U.S.C. 103(a) as being unpatentable over Pastan et al. (2000, US 6,011,002, the '002 patent) in view of Radhakrishnan et al. (1999, J Mol. Biol. 286:151-162) is maintained for reasons of record and for reasons set forth below.

Applicants' traverse the rejection (Response of 12 October 2006, page 3). The reasons for the traversal are that:

a) neither Pastan nor Radhakrishnan recite the claimed SEQ ID NOs.

b) Neither reference teaches a linker required for each of the claimed SEQ ID NOs, nor provides the requisite motivation or suggestion to make the specifically claimed linker.

Applicant's arguments have been fully considered but are not found to be persuasive for the following reasons:

While the '002 patent does not specifically teach a circularly permuted molecule wherein the molecule is a molecule of SEQ ID NO:35, the patent does teach preferred opening sites within the molecule are selected in regions of the protein that do not show highly conserved sequence identity between various members of the protein family (i.e the interferon type 1 family). The Radhakrishnan reference teaches that these molecules have a common conserved structural core which consists of helix A (residues 8-21) AB2 loop (residues 34-39), helix B (residues 53-68), helix C (residues 79-100) and helices D and E. Thus, the skilled artisan would be directed to make a molecule of SEQ ID NO:35, wherein the breakpoint or opening site is located between residues 27 and 28, since this site is not contained within a common conserved core structure.

The '002 patent teaches that the amino and carboxy ends of the molecule of interest may be joined together directly or through a linker (column 2, lines 9-11). The linker refers to a molecule used to join the amino and carboxyl termini of a protein and is capable of forming covalent bonds to both the amino and carboxyl terminus. Suitable linkers are well known in the art and include...peptide linkers, such as the linkers described in the instant invention (column 5, lines 26-38). The '002 patent teaches that good candidates for circular permutation are proteins in which the termini of the original protein are in close proximity and favorably oriented; under these circumstances introduction of a linker will have relatively little effect. The linker may be of any length (column 8, lines 45-56). The '002 patent additionally teaches "it is desirable to use a linker that preserves the spacing between the termini comparable to the unpermuted or native molecule....The most common and simple example is a peptide linker that typically consists of several amino acids joined through peptide bonds to the termini of the native protein....the linkers will be joined through peptide bonds to the alpha carbon amino and carboxyl groups of the terminal amino acids" (column 8, lines 57- bridging column 9, line 6).

Applicants argue that the circularly mutated molecule is not obvious over the prior art because the molecule of SEQ ID NO:35 comprises a GD linker. However, a GD linker is consistent with teachings in the art, which teach the presence of these two amino acid residues in linker domains (See, for exemplary purposes only, Table 3 in Argos, 1990. J Mol. Biol 211:943-958).

In reviewing the specification (page 9), it is noted that methods for making the polypeptide (ie cloning process for producing clone encoding polypeptide of the claimed invention) of the instant invention was not clearly set forth. Thus, the Examiner cannot determine if the GD linker is an artifact of the cloning process and therefore cannot determine if the claimed polypeptide is not obvious over the prior art.

Applicants have not shown any criticality of the GD linker of to the properties of the molecule of SEQ ID NO:35. The molecules of the instant invention (the elected sequence of SEQ ID NO:35 and SEQ ID NO:34, discussed in the response of 12 October 2006, page 3) have different linker sequences; thus the use of any one particular linker sequence has not produced unexpected results or imparted novel characteristics to the circular permuted molecule.

The '002 patent gives guidance on how to choose a linker sequence; Radhakrishnan et al teach the crystalline structure of the human IFN-β molecule and mouse IFN-β molecule, from which one may determine the spacing between the termini. Thus, using these combined teachings, it would require only routine optimization of operating parameters to produce a circularly permuted interferon molecule comprising the linker of the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or nonobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.) Furthermore, minor changes in chemical configuration or design of a molecule over that disclosed in the prior art are prima facie obvious, since applicants have not explained practical advantages of differences in (DNA) structure between claimed sequence and prior art. See Ex parte Anderson 30 USPQ2d 1866, 1993.

Conclusions

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER